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(54) WOUND DRESSING

(71) We, UNIVERSITY OF THE PACIFIC, a corporation organised and existing under the laws of the State of California, United States of America, of West Memorial Finance Center, 3622 Stagg Way, Stockton, California 95204, United States of America,

do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to dressings for a lesion or wounds. More particularly it relates to dressings of the type having a water and plasma soluble flexible body that is capable of forming an artificial eschar with the exudates issuing from a lesion to which the dressing is applied. The dressing may contain medicaments or therapeutic agents for beneficially treating the wound. Such dressings can sequentially dissolve in the tissue of the wound, thereby sequentially releasing medicaments in the wound tissue.

U.S. Patent No. 3,328,259 to Anderson describes dressings similar to those provided by the present invention. The dressings in the Anderson patent are stated to be water and plasma soluble and when applied to a wound are capable of forming an artificial eschar to protect the same while gradually dissolving and releasing therapeutic agents. As described in the document such dressings have numerous advantages over previously used dressings. For example. ordinary gauze type dressings become incorporated into the granulation tissue at the surface of the lesion so that the new healthy tissue may be pulled off when the dressing is removed. Ordinary dressings are undesirably bulky, have to be changed at frequent intervals and cause an increase in maceration with subsequent prolongation of healing time. Occlusive dressings, such as creams, lotions, ointments and the like, must be rubbed into the open lesion thereby producing pain. Also, removal of occlusive materials is difficult. Such materials are generally not satisfactory because they do not permit air contact with wounds and like ordinary dressings cause an increase in maceration of the healing tissue.

While the dressing disclosed in U.S. Patent No. 3,328,259, in common with the present dressing, provides many of these advantages over the older prior art, the principal component of the dressing according to the present invention provides significant advantages over the materials used in the U.S. Patent referred to above. Specifically the prior dressing is formed from certain water and plasma soluble cellulose derivatives. In the present invention the dressing comprises a water soluble flexible body that can form an artificial eschar with the moist elements at the situs of the wound, which body comprises a plasma and water soluble dextran. As used herein, the term "plasma" means the liquid part of the blood removed by centrifuge. The dextran based, preferably flexible bodies of the present invention exhibit significant improvements in increased rates of solution in water and plasma in comparison with the flexible body dressings of the prior art. For example, a dressing as disclosed in Example 4 of the U.S. Patent requires 1 minute and 10 seconds to dissolve in water. Dressings of the present invention are capable of dissolving in 30 seconds or less.

In contrast to ordinary gauze type dressings and occlusive type dressings, the present flexible hydrophilic film is applied without inunction, is non-irritating to the lesion, is self-adhesive to the lesion, is easily removable by immersion for a few seconds in water or it may be left in place to be absorbed systemically and excreted by the body. While being absorbed, therapeutic agents or medicaments may be gradually released to the wound. The present type of dressing is thus a highly efficient dosage form for local therapy.

Dextran polymers have the additional advantage in that they are generally available in a higher degree of purity than the cellulose materials of the prior art. Considering the application of the dressing produced therewith and the fact that it dissolves into the wound to be carried systemically indicates the significance of such a fact. The present dextran polymers are fully compatible with the human body and present substantially no question of toxicity or other potential

health hazards. The cellulose materials of the prior art are not known to be completely free from any such complications. Moreover, the present materials have utility with all patients. The prior art is not equally applicable to the extent that it suggests the use of sodium salts of cellulose derivatives in the formation of dressings. In certain instances the systemic incorporation of the sodium cellulose salts may introduce an undesirable excess of sodium in the body, taxing the body salt balance and inducing stress.

In the broader aspects of the present invention, the general considerations described in U.S. Patent No. 3,328,259 are applicable except of course for the use of the instant dextran polymers instead of cellulose derivatives. In general the dextran polymer of the present invention will have an average molecular weight of about 40,000 to 100,000. For example, dressings made from specific dextran polymers having an average molecular weight of 40,000, 70,000 and 86,900 have been found to be satisfactory.

Preferably before use the formulation is reduced in moisture content so that the water is 5—15% by weight of the dressing and the dextran polymer is 60—90% by weight of the dressing thereby providing a solid self-supporting film-like material of suitable thickness. The dextran polymer is in an integral porous non-discrete form. The preferred form of the present body is an aerated foam. This provides oxygen to the wound and also is more rapidly soluble compared with a non-foamed embodiment.

Where an aerated foam is the desired form, it is beneficial to include a surfactant in the formulation as a foaming agent. The surfactant also serves as an emulsifier. Such surfactant may be anionic, cationic, nonionic or amphoteric and is selected for its compatibility and stability with the other components in the formulation. Examples of suitable surfactants are the ionic dioctyl sodium sulfosuccinate, the nonionic polyoxyethylene sorbitan monolaurate, and the amphoteric commercial material available under the name Miranol 2MCA Modified.

The film or body of the present invention may include antiseptics, steroids, germicidals, anesthetics, antibiotic materials and the like to minimize infection, pain and generally promote healing. Such materials are herein referred to generally as medicaments. Specifically it is contemplated to include mafenide or povidone iodine into the present dressing body or film. In other embodiments silver salts such as silver nitrate, silver sulfadiazine, gentamicin and salts thereof and local anesthetics such as lidocaine, benzocaine and salts thereof are specifically contemplated. Such medicaments are advantageously applied to wounds through the present dressing as distinguished from the dosage forms previously used therefor.

Some residual moisture of the order of 5—15% by weight is desired so as to avoid a film or body that is either too brittle or too soft when outside of these limits. To this end plasticisers or humectants such as glycerin, sorbitol, or propylene glycol may be included in the formulation. Optional ingredients may include anti-oxidants and stabilizers for example. Also consistent with prior procedures, the present dressing may be sterilized, for example with ethylene oxide or CO_2. Packaging is preferably in air proof and moisture proof material.

The invention will now be described by way of the following examples.

Example 1

As a typical solution for the preparing of hydrophilic aerated dry films of this invention, 16 grams of dextran with an average molecular weight of 70,000 is dissolved in 73.4 grams of water at 50°—70°C. To this solution, 10.4 grams of sorbitol solution and 0.2 grams of Miranol 2MCA Modified were added. After whipping the film forming solution for 10—15 minutes, the resultant foam may be spread to a uniform depth onto a Teflon coated drying surface and dried at 50—60°C to a moisture content of 5—15% ("Teflon" is a registered Trade Mark). Such a film is aerated and one square inch thereof dissolves in 0.1 ml. of water at room temperature in less than 30 seconds.

Example 2

20 grams of dextran with an average molecular weight of 86,900 together with 8 grams of polyoxethylene sorbitan monolaurate, 16 grams of glycerin, and an amount of mafenide acetate equivalent to 8.5%, by weight, of the dry film, are dissolved in approximately 50 grams of water. After aerating the film forming solution by whipping with a mixer, the resultant foam is cast, dried, and cut to appropriate size.

Example 3

18 grams of dextran with an average molecular weight of 40,000, 10.4 grams of sorbitol solution and 1 gram of dioctyl sodium sulfosuccinate are dissolved in approximately 70 grams of water. In addition, silver salts, such as silver nitrate and silver sulfadiazine, may be added to the film forming solution to provide their therapeutic effects.

Examples 4 and 5 illustrate the incorporation of specific therapeutic agents in dressings according to the invention; namely, povidone iodine in Example 4 and lidocaine hydrochloride in Example 5.

Example 4

A film forming solution is prepared having the following composition:

	Gms.
Povidone Iodine	2.4
Preservative	0.2
Glycerin	0.5
Sorbitol Solution	2.0
Tween 20 (Tween is a registered Trade Mark)	1.0
Dextran (Avg. Wt. 86,900)	77.9

After casting and drying, the composition of aerated dry foam is as follows:

Povidone Iodine	2.4
Preservative	0.2
Glycerin	0.5
Sorbitol Solution	2.0
Tween 20 (Tween is a registered Trade Mark)	1.0
Dextran (Avg. Wt. 86,900)	16.0
Water	2.4

Example 5

A film forming solution is prepared having the following composition:

Lidocaine Hydrochloride	0.2
Dextran (Avg. Wt. 70,000)	15.0
Propylene Glycol	8.0
Alcohol	10.0
Water	66.8

The above solution may be packaged in a pressurized aerosol utilizing suitable propellants. In this manner, the hydrophilic foam may be generated immediately prior to use by actuating the aerosol.

WHAT WE CLAIM IS:—

1. A wound dressing comprising a water soluble flexible body that can form an artificial eschar with the moist elements at the situs of the wound, which body comprises a plasma and water soluble dextran.

2. A dressing according to Claim 1 wherein the dextran body is porous.

3. A dressing according to Claim 1 or Claim 2 wherein the dextran has an average molecular weight in the range of forty thousand to one hundred thousand.

4. A dressing according to any preceding claim wherein the dextran comprises 60—90% by weight of the flexible body.

5. A dressing according to any preceding claim wherein the flexible body contains 5—15% by weight of water.

6. A dressing according to any preceding claim wherein the flexible body contains medicaments preselected to treat the wound to be covered by the flexible body.

7. A dressing according to any preceding claim wherein the flexible body is in the form of an aerated foam and contains sufficient surfactant to promote formation of said foam.

8. A wound dressing as claimed in claim 1 and substantially as described herein and with reference to the examples.

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